SPINEWAVE

FEB 12 2010

510(k) Summary
CapSure® PS System

Submitter Information

Spine Wave, Inc.
Three Enterprise Drive
Suite 210
Shelton, CT 06484
Telephone: 203-712-1839
Telefax: 203-944-9493

Contact: Roaida Rizkallah
Date Prepared: January 13, 2010

Device Information

Trade name:	CapSure® PS System
Common name:	Pedicle Screw Spinal System
Classification:	Class II per 21 CFR 888.3070
Classification Name:	Pedicle Screw Spinal System
Product Code:	MNI, MNH

Device Description

The CapSure® PS System consists of a selection of non-sterile, single use titanium alloy rod, screw, and cross connector components that are assembled to create a rigid spinal construct. The components of the CapSure® PS System are attached to the non-cervical spine in order to stabilize the spine during fusion of the vertebral bodies, and are intended to be removed after spinal fusion is achieved.

This purpose of this submission is to gain clearance for the addition of the LP Cross Connector component to the CapSure® PS System. The LP Cross Connector is a non-sterile, single use, titanium allow device which can be used with the CapSure® PS System for added stability. The LP Cross Connector is available in lengths ranging from 38mm to 81mm.

Intended Use

When used as a pedicle screw fixation system of the noncervical spine in skeletally mature patients, the CapSure® PS System is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The CapSure® PS System is also indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3-S1), and for whom the device is intended to be removed after solid fusion is attained.

Substantial equivalence

The CapSure® PS System described in this submission is substantially equivalent to the following devices:

Predicate Device	Manufacturer	510(k) No.
CapSure® PS System	Spine Wave, Inc.	K083743, K083353

In addition, mechanical testing demonstrated that the CapSure® PS System is equivalent to the predicate CapSure® PS System. The differences between the CapSure® PS System and the predicate device do not raise any new questions of safety or effectiveness. Thus, the CapSure® PS System is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Spine Wave, Inc.
% Ms. Roaida Rizkallah
Senior Regulatory Affairs Specialist
Three Enterprise Drive, Suite 210
Shelton, Connecticut 06484

FEB 12 2010

Re: K100122
Trade/Device Name: CapSure® PS System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, MNH
Dated: January 13, 2010
Received: January 15, 2010

Dear Ms. Rizkallah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K100122

Device Name: CapSure® PS System

Indications for Use:

When used as a pedicle screw fixation system of the noncervical spine in skeletally mature patients, the CapSure® PS System is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The CapSure® PS System is also indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3-S1), and for whom the device is intended to be removed after solid fusion is attained.

Prescription Use __√____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100122